

10091627

## SECTION IV

### 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

**Smith & Nephew Instrument Trays**  
**Date Prepared: June 2, 2009**

JUL - 2 2009

#### **A. Submitter's Name:**

Smith & Nephew, Inc., Endoscopy Division  
150 Minuteman Road  
Andover, MA 01810

#### **B. Company Contact**

Christina Flores  
Regulatory Affairs Specialist II  
T: 508-261-3705  
F: 508-261-3620  
Christina.flores@smith-nephew.com

#### **C. Device Name**

Trade Name:	Smith & Nephew Instrument Tray
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes and Other Accessories
Class:	II
Product Code:	KCT
Classification Number:	21 CFR §880.6850

#### **D. Predicate Devices**

The subject Smith & Nephew Instrument Trays are substantially equivalent in Intended Use and Fundamental Scientific Technology to the following legally marketed device in commercial distribution: Smith & Nephew Instrument Tray cleared under K073551 and Smith & Nephew Instrument Trays cleared under K090562.

#### **E. Description of Device**

The Smith & Nephew instrument trays are designed to contain and protect reusable surgical instruments during transport, sterilization, and storage and to allow optimal exposure of the tray's contents to sterilant during the sterilization process.

## **F. Intended Use**

Smith & Nephew instrument trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The subject instrument trays are suitable for use in prevacuum steam and high temperature gravity steam sterilization methods. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

Validated Sterilization Parameters:

Method	Temperature	Exposure Time	Drying Time
Pre-vacuum steam	132C (270F)	4 minutes	30 minutes
High Temperature Gravity Steam	132C (270F)	15 minutes	70 minutes

## **G. Comparison of Technological Characteristics**

The subject Smith & Nephew instrument trays have the same fundamental technological characteristics as the unmodified predicate device. The subject trays are substantially equivalent in design, materials and intended use to the predicate device. There are no significant differences between the proposed and predicate devices that raise new questions of safety or efficacy.

## **H. Summary Performance Data**

Performance testing was conducted in accordance with AAMI ST77:2006 *Containment Devices for reusable medical device sterilization*.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Christina Flores  
Regulatory Affairs Specialist II  
Smith & Nephew, Incorporated  
Endoscopy Division  
150 Minuteman Road  
Andover, Massachusetts 01810

JUL - 2 2009

Re: K091627  
Trade/Device Name: Smith & Nephew Instrument Trays  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: II  
Product Code: KCT  
Dated: June 2, 2009  
Received: June 3, 2009

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

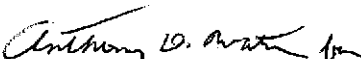
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

  
Susan Runner, D.D.S., M.A.  
Acting Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(K) Number: K091627

Device Name: Smith & Nephew Instrument Trays

Indications for Use: Smith & Nephew instrument trays are intended to contain Smith & Nephew reusable surgical instruments for convenient organized storage, sterilization and transport between usages. The subject instrument trays are suitable for use in prevacuum steam and high temperature gravity steam sterilization methods. The subject instrument trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated sterilization wrap in order to maintain sterility of the enclosed devices.

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Device models that are the subject of this pre-market notification:

REF	Description
72202042	Elite Premium II Shoulder Arthroscopy System Tray
72202044	Elite Premium Instability System Tray

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

## SECTION II

K091627 Additional Information  
7/1/09

510(k) Number: K091627